

### **REMARKS**

Claim 1 has been amended to recite a "fat-soluble vitamin dispersed in a matrix consisting of an emulsion-forming composition...." Support for this amendment is found in the specification at, for example, page 5, lines 7-11 and page 7, lines 7-24; in original claims 1 and 2; and in Example 1. See, *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

It is submitted that no new matter has been introduced by the foregoing amendment. Approval and entry of the amendment are respectfully solicited.

### **CITATION OF FOREIGN LANGUAGE DOCUMENT**

All of the rejections in the pending Office Action rely on a German language EP patent publication, namely, Leuenberger, EP 0 565 989 ("Leuenberger '989"). Instead of obtaining an English translation of Leuenberger '989, the Examiner relied on U.S. Patent No. 5,668,183 ("Leuenberger '183") as a translation of Leuenberger '989. (Paper No. 10 at 2, 4, and 6.)

We respectfully submit that the Examiner's reliance on Leuenberger '183 as an accurate translation of Leuenberger '989 is misplaced because he has failed to show any relationship between the EP document cited and the U.S. patent offered as a translation.

The only apparent relationship between the EP document and the U.S. patent is that they both claim priority to the same two Swiss priority applications. The later-in-time U.S. application does not claim benefit to the EP document cited by the

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Examiner. Where, as here, there is no direct relationship between a foreign patent document that may qualify as prior art and a U.S. patent, the Examiner bears the initial burden to demonstrate the propriety of using the proffered U.S. patent as a faithful translation of the asserted document. None of the MPEP citations offered by the Examiner support the argument offered in the present Office Action that a U.S. patent with no apparent direct link to a Germany language EP patent document may be used as a translation of the EP patent document. For the reasons set forth above, it is respectfully submitted that all of the rejections citing the Leuenberger '989 patent must be withdrawn.

With a view toward furthering prosecution, and without waiving the above position, we address the rejections in the office Action based on Leuenberger '183 patent.

### **Rejection under 35 USC § 102**

Claim 1 and 3-14 were rejected under 35 USC §102(b) as anticipated by Leuenberger '989, relying upon Leuenberger '183. (Paper No. 10 at 2.)

For the reasons set forth below, the rejection, respectfully is traversed.

Leuenberger '183 discloses "stable, cold water-dispersible preparations of fat-soluble substances ... contain[ing] a water-soluble or water-dispersible ***lignin derivative as the matrix component.***" (Col. 1, lines 43-46.) Lignins are identified, in Leuenberger '183, as "irregular polymers of methoxylated phenylpropane monomers having a molecular weight estimated to be at least 20 kD." (Col. 2, lines 11-15.)

In making the rejection, the Examiner contended only that Leuenberger '989 "discloses gelatin or gum arabic powder compositions for vitamins where the powder composition has a particle size within the instant range. [Leuenberger] '989 also discloses the instant vitamins and ranges/amounts of ingredients." (Paper No. 10 at 2.)

Ex. 4  
As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). There must be **no difference between what is claimed and what is disclosed in the applied reference**. *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). "Moreover, it is incumbent upon the Examiner to **identify wherein each and every facet** of the claimed invention is disclosed in the applied reference." *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990). The Examiner is required to point to the disclosure in the reference "**by page and line**" upon which the claim allegedly reads. *Chiong v. Roland*, 17 USPQ2d 1541, 1543 (BPAI 1990).

Initially, we note that the rejection fails to identify wherein Leuenberger '183 each and every element of claim 1, as amended, is found. At best, the rejection generically characterizes Leuenberger '183 as disclosing "gelatin or gum arabic powder compositions for vitamins where the powder composition has a particle size within the instant range." The rejection fails to identify where such disclosures are to be found.

We have found only a single description of gum arabic or gelatin as a matrix in Leuenberger '183. (See Col. 1, lns 15-34). But that description is located in the section entitled "Background of the Invention" and is not accompanied by a

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description of the diameter of the fat soluble vitamin droplets in the powder composition.

Thus, the rejection is legally deficient at least because (1) it fails to identify by page and line number where each and every element of, e.g. claim 1, may be found in Leuenberger '183 and (2) it fails to demonstrate that Leuenberger '183 discloses each of the elements of, e.g. claim 1, arranged as in the claim. It appears that the rejection borrows disclosure of the disadvantages of certain known compositions and combines them with certain new elements disclosed in the "Detailed Description" section of the '183 patent. But this kind of rearrangement of disclosure is expressly forbidden in a §102(b) rejection. (See *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir 1984) ("Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.")) For this reason alone the rejection should be withdrawn.

With a view toward furthering prosecution, however, claim 1 has been amended to recite the transitional phrase "consisting of." Therefore, the rejection has been rendered moot.

Accordingly, for the reasons set forth above, the rejection should be withdrawn.

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### **Rejections under 35 USC § 103**

Claims 1 and 3-15 were rejected under 35 USC §103(a) as being unpatentable over Leuenberger '989, relying upon Leuenberger '183. (Paper No. 10 at 4.)

For the reasons set forth below the rejection, respectfully is traversed.

Leuenberger '183 is summarized above.

In making the rejection, the Examiner asserted that Leuenberger '989 discloses "gelatin or gum arabic powder compositions for vitamins where the powder composition has a particle size within the instant range." (Paper No. 10 at 4.) The Examiner acknowledged, however, that Leuenberger '989 "does not teach the moisture content of the powder...." (*Id.*)

The Examiner offered nothing to fill the acknowledged gap, but merely concluded that "it would have been obvious ... to achieve the instant moisture content based upon the motivation of insuring dryness and good flowability." (*Id.*)

As is well settled, the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

As we noted in our earlier argument<sup>1</sup>, the rejection continues to use the wrong standard for determining obviousness. The rejection relies upon an "**obvious to ... achieve**" standard that is not found in the statute or precedential authority. Whether

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or not it would be "obvious to achieve" an element identified in a claim is irrelevant. An obviousness analysis requires an Examiner to identify the motivation or suggestion to modify a cited document to arrive at the claimed invention as a whole. Because the rejection relies on an improper standard – an "obvious to achieve" standard – the rejection is deficient as a matter of law and should be withdrawn for this reason alone.

Notwithstanding the legally insufficient nature of the rejection, we demonstrate below why the rejection is also devoid of the requisite facts to support a *prima facie* case under § 103.

As is fundamental, a *prima facie* case of obviousness must be based on facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When the rejection is not supported by facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). In the absence of a *prima facie* case of obviousness, an applicant who complies with the other statutory requirements is entitled to a patent. See *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Further, "to establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03 (8<sup>th</sup> ed. Rev. 1, February 2003, p. 2100-128) (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)). The rejection, however, identifies nothing in Leuenberger '183 which discloses or suggests a "matrix consisting of an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof..." as recited in amended claim 1.

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<sup>1</sup> See *Response to Office Action Including Amendment* dated September 19, 2002.

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Moreover, Leuenberger '183 discloses the use of a lignin as the matrix. However, lignin is excluded from the matrix recited in the present claims.

Furthermore, the Examiner has not identified where in Leuenberger '183 there is disclosed a powder composition with the presently claimed emulsion forming compositions in combination with a fat soluble vitamin in the form of droplets having a diameter of 70-150nm. Nor has the rejection identified why such a powder composition would have been suggested by Leuenberger '183 to one skilled in the art. But that too was the Examiner's burden. For these reasons, the rejection is factually deficient and should be withdrawn.

Moreover, if a proposal for modifying one or more documents renders such documents inoperable or destroys their intended purpose, then the requisite motivation to make the modification would not have existed, and any rejection based on such a proposed modification would have to fail. (See, e.g., *In re Fritch*, 23 USPQ2d 1780, 1783, n. 12 (Fed. Cir. 1992) and *In re Ratti*, 123 USPQ 349, 352 (CCPA 1959) (holding the suggested combination of references improper under § 103 because it "would require a substantial reconstruction and redesign of the elements shown in [a prior art reference] **as well as a change in the basic principles under which [that reference's] construction was designed to operate.**")

Leuenberger '183 discloses the use of a matrix in which the major component is lignin. (Col. 1, lines 43-46.) Leuenberger '183, however, discloses that lignin is superior to gelatin and gum arabic because they "do not always have the desired dispersibility in cold water...." (Col. 1, lines 32-34.) In fact, Leuenberger '183 actually teaches away from using gelatin and gum arabic. (Col. 1, lines 18-34.) To

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modify Leuenberger '183 as proposed in the rejection would require using gelatin or gum arabic in place of lignin. But as noted above, it is impermissible to modify a document to fundamentally alter the principles under which it was designed to operate.

For this additional reason, the rejection should be withdrawn.

Claim 17 was rejected under 35 USC §103(a) as being unpatentable over Leuenberger '989, relying upon Leuenberger '183, in view of Finnan *et al.*, U.S. Patent No. 4,830,859 ("Finnan"). (Paper No. 10 at 6.)

For the reasons set forth below the rejection, respectfully is traversed.

Leuenberger '183 is summarized above.

Finnan discloses "a process for preparing lubricated **water-soluble vitamin** powder ... [which] is directly compressible into tablets." (Col. 1, lines 10-15.)

In making the rejection, the Examiner relied on his previous characterization of Leuenberger '989. (Paper No. 10 at 6.) The Examiner acknowledged, however, that Leuenberger '989 "does not teach incorporating the powder into tablets." (*Id.* at 6.)

To fill the acknowledged gap, the Examiner relied on Finnan as disclosing "formation of vitamin powder into tablets." (*Id.*)

The Examiner then summarily concluded "it would have been obvious ... to form the powder of [Leuenberger] '989 into tablets with the motivation of providing a convenient dosage form for administration of the vitamin." (*Id.*)

As is well settled, a rejection under § 103 must demonstrate **where** in the cited documents there was a suggestion which would have "strongly motivated" one to carry out the invention as claimed. *Ex parte Graselli*, 231 USPQ 393, 394 (Bd. App.



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1986). The type of motivation which would have "**impelled**" one to do so (*Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993)), and the type of suggestion that the changes "**should**" be made. *Ex parte Markowitz*, 143 USPQ 303, 305 (Bd. App. 1964).

Leuenberger '183 discloses water-dispersible compositions made from **fat soluble vitamins**. (Col. 1, Ins 43-45). Finnan discloses processes for preparing lubricated **water-soluble vitamins**. The rejection points to nothing in Leuenberger '183 or Finnan that discloses, let alone suggests that a tableting process for **water-soluble** vitamins would work with powder containing **fat soluble** vitamins. Absent such a disclosure or suggestion in either document, the rejection is left with only Examiner conjecture. An Examiner's belief or conjecture, however, is no substitute for statutory prior art. *In re Kratz*, 201 USPQ 71, 76 (CCPA 1979) (citing *In re Antonie*, 195 USPQ 6 (CCPA 1977) ("We have previously rejected the argument that undirected skill of one in the pertinent art is an adequate substitute for statutory prior art.")) For this reason alone, the rejection is deficient and should be withdrawn.

Notwithstanding the lack of motivation or suggestion to combine Leuenberger '183 and Finnan, even if such documents were combined, they would still fall short of the claimed invention. As noted earlier, the rejection identifies nothing in Leuenberger '183 which discloses or suggests a "matrix consisting of an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof...." In fact, Leuenberger '183 discloses the use of a lignin as the matrix to avoid the stated infirmities of gums and gelatin. Claim 17, which depends from claim 1,

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necessarily excludes lignin from the matrix recited. And, the rejection has identified no disclosure in Finnan that would remedy this factual gap.

For this additional reason, the rejection is factually deficient and should be withdrawn.

As noted in response to the § 102 rejection, the modification of Leuenberger '183 as suggested by the Examiner would require a fundamental change in the basic principles of Leuenberger '183, which is not disclosed or suggested by either Leuenberger '183 or Finnan, namely replacing lignin with gelatin or gum arabic. Where, as here, the required motivation to make the modification does not exist, any rejection based on such a proposed modification must fail. (See, e.g., *In re Fritch*, 23 USPQ2d 1780, 1783, n. 12 (Fed. Cir. 1992) and *In re Ratti*, 123 USPQ 349, 352 (CCPA 1959)).

Accordingly, the suggested modification of Leuenberger '183 and combination with Finnan is improper. For this additional reason, the rejection should be withdrawn.

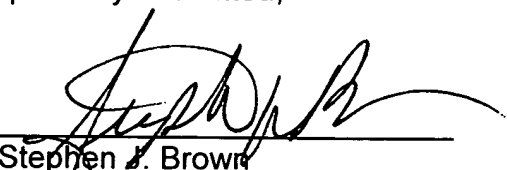
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Accordingly, for the reasons set forth above, entry of the amendment, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, Alexandria, VA 22313-1450, on April 16, 2003.

  
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